REMARKS

Reconsideration and withdrawal of the claim rejections are requested in view of the amendments and remarks herein.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, 4, 5, 16-19 and 21-38 are under consideration in this application. Withdrawn claims 2, 3, 6-15 and 20 are cancelled. Applicants reserve the right to pursue the subject matter of cancelled claims in continuing application.

No new matter is added.

II. THE DOUBLE-PATENTING REJECTION IS OVERCOME

Claims 1, 4, 5, 16-19 and 21-38 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 210 and 211 of U.S.S.N. 09/760,574 ("the '574 application"). The rejection is traversed.

The claims of the instant application relate to the administration to a bovine or porcine of a combination vaccine, comprising (a) a complex of a cationic lipid and a plasmid expressing an immunogen of a bovine or porcine pathogen and (b) a second vaccine, immunogenic, or immunological composition that is an inactivated, attenuated live, subunit or recombinant vaccine, immunogenic, or immunological composition.

Claims 210 and 211 of the '574 application are directed to method for inducing an immunological response against a bovine pathogen (claim 210), specifically BRSV (claim 211) in a bovine comprising administering a DNA plasmid vaccine, substantially as described in part (a) of claim 1 of the instant application. However, the claims of the '574 application do not encompass, nor do they render obvious, the administration of the DNA vaccine or immunogenic or immunological composition of claim 1(a) in combination with the conventional or recombinant vaccine or immunogenic or immunological composition of claim 1(b).

The Office Action alleges that the instant claims and those of the '574 application are not patentably distinct because they relate to "inducing an immune response against BRSV in a bovine comprising administering to the bovine the same composition". As discussed above, the composition of the '574 application and the composition of the instant application are **not** "the same composition", as argued in the Office Action. The composition of the '574 application is a DNA plasmid vaccine. The instant claims require an additional component, namely a second vaccine that can be "conventional" (*i.e.* inactivated, attenuated live or subunit) or recombinant.

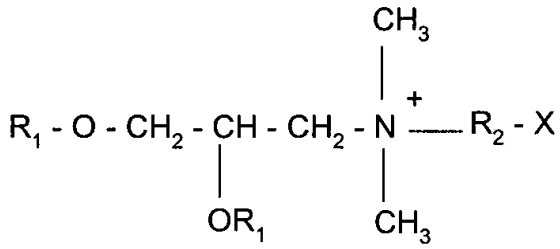
This component is not required by claims 210 and 211 of the '574 application or by claims 84 and 96, from which they depend. Therefore, the composition is not the same. The argumentation advanced in the Office Action with respect to this point is akin to the argument that a vaccine for measles and mumps is the same as a vaccine for measles alone.

Accordingly, the subject matter of this application and the '574 application are patentably distinct, and reconsideration and withdrawal of the double patenting rejection are requested.

III. THE REJECTION UNDER 35 U.S.C. §103 IS OVERCOME

Claims 1, 4, 5 and 16-19 were rejected under 35 U.S.C. §103, as allegedly being unpatentable over Taylor *et al.* in view of Harris *et al.* and further in view of Bonnem *et al.* and Baker *et al.* The rejection is traversed.

As discussed above, the present invention provides a method for obtaining an immunogenic response comprising administering to a bovine or porcine a combination of (a) a DNA vaccine or immunogenic or immunological composition against a bovine or porcine pathogen comprising at least one plasmid containing and expressing a nucleotide sequence encoding an immunogen of the bovine or porcine pathogen, and a cationic lipid containing a quaternary ammonium salt, of the formula



in which R_1 is a saturated or unsaturated linear aliphatic radical having 12 to 18 carbon atoms, R_2 is an aliphatic radical containing 2 or 3 carbon atoms, and X a hydroxyl or amine group **and** (b) an inactivated, attenuated live, subunit or recombinant vaccine or immunogenic or immunological composition against a bovine or porcine pathogen. The two vaccines or immunogenic or immunological compositions can be administered concurrently or sequentially. Sequential administration can include the use of a prime boost regimen, as described in the specification (for example, in the paragraph beginning on page 26, line 17).

The lipid can be DMRIE and the vaccine or composition can further comprise DOPE. The vaccine or composition can also further comprise GM-CSF or an expression vector

containing and expressing a nucleotide sequence encoding GM-CSF. It should be noted that GM-CSF is NOT the component of claim 1(b); rather, it is an additional, optional component.

In the elected species, the bovine pathogen is bovine respiratory syncitial virus (BRSV). The immunogen can be BRSV F or BRSV G. For instance, the immunogen can be BRSV F or G, modified by substitution of the BRSV F signal sequence with a human tPA signal sequence, and/or by deletion of the transmembrane domain and/or the C-terminal portion of the protein.

As discussed in the attached Declaration under 37 CFR 1.132 by Dr. Jean-Christophe Audonnet, an inventor of the instant application and an expert in the art of veterinary vaccines, none of the cited documents teaches or suggests a method for obtaining an immunogenic response using (a) a complex of a cationic lipid and a plasmid expressing an immunogen of a bovine or porcine pathogen and (b) a second vaccine, immunogenic, or immunological composition that is an inactivated, attenuated live, subunit or recombinant vaccine, immunogenic, or immunological composition. Furthermore, none of the cited documents teaches or suggests the sequential use of such vaccines or compositions, particularly in a prime boost regimen.

In addition, because none of the cited references teaches or suggests a multi-valent vaccine, the well-known problem in the art of efficacy interference is not addressed. As discussed in the Declaration by Dr. Audonnet, the results presented in the current application are surprising and unexpected because one of skill in the art, appreciating the problem of efficacy interference, would not have a reasonable expectation of success in combining the compositions of parts (a) and (b) of claim 1 to obtain an immunological response. The success demonstrated is contrary to what the skilled artisan might expect, given the known problem of efficacy interference in the art.

For reasons discussed in the Declaration by Dr. Audonnet, the combination of Taylor *et al.*, Harris *et al.*, Bonnem *et al.* and Baker *et al.* does not result in the claimed invention. There is no teaching in any of the cited references, nor has the Examiner pointed to a place where even the suggestion was made, of administering a DNA vaccine and a second vaccine, either in combination or sequentially. Taylor *et al.* does not even teach a DNA plasmid vaccine, as alleged in the Office Action, but rather, teaches a BRSV antigen expressed in recombinant vaccinia virus. Therefore, the vaccine proposed by Taylor *et al.* is neither a combination

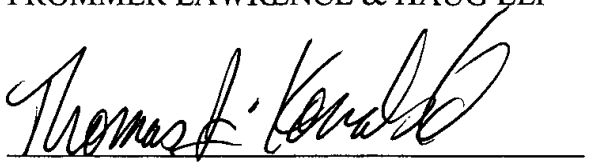
vaccine, nor a DNA plasmid vaccine, both of which are requirements of the instant claims. None of the other cited references cure these deficiencies.

In view of the herein arguments and the accompanying Declaration by Dr. Audonnet, reconsideration and withdrawal of the 35 U.S.C. §103 rejection are respectfully requested.

CONCLUSION

In view of these amendments and remarks, the application is believed to be in condition for allowance, or at least in better condition for appeal. Entry of this Amendment, early and favorable reconsideration of the application, reconsideration and withdrawal of the rejections, and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: 

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